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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,155	12/02/2003	John S. Babcook	ABGENIX.073A	5639

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

RINAUDO, JO ANN S

ART UNIT PAPER NUMBER

1644

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/727,155

Applicant(s)

BABCOOK ET AL.

Examiner

Jo Ann Rinaudo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-56 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

1. It is noted that claims 52-56 are directed to the "use" of an antibody to Tumor Necrosis Factor-alpha. "Use" claims are non-statutory under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example Ex parte Dunki , 153 USPQ 678 (Bd. App. 1967) and Clinical Products, Ltd v. Brenner, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). See MPEP 2173.05(q).
2. For the restriction purpose, Claims 52-56 have been interpreted as a method of preparing a medicament using an antibody.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-43 and 46, drawn to a monoclonal antibody to Tumor Necrosis Factor-alpha, in a pharmaceutical carrier, classified in class 530, subclass 388.23.
 - II. Claims 44 and 45, drawn to a method of assaying the level of Tumor Necrosis Factor-alpha in blood, classified in class 435, subclass 7.1.
 - III. Claims 47 and 48, drawn to drawn to a method of treating neoplastic disease by administering an antibody to Tumor Necrosis Factor-alpha, classified in class 424, subclass 141.1.

- IV. Claims 49 and 50, drawn to a method of treating an immun-mediated inflammatory disease by administering an antibody to Tumor Necrosis Factor-alpha, classified in class 424, subclass 141.1.
- V. Claim 51, drawn to a method of inhibiting Tumor Necrosis Factor-alpha induced apoptosis by administering an antibody to Tumor Necrosis Factor-alpha, classified in class 424, subclass 141.1.
- VI. Claims 52-56, drawn to a method of preparation of a medicament with a monoclonal antibody to Tumor Necrosis Factor-alpha, classified in class 424, subclass 145.1.

4. Group I and Groups II-VI are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process. The antibody of Group I can be used for affinity purification, in addition to the methods of treating, detecting and preparation of a medicament recited in Groups II-VI.

5. Groups II-VI are patentably distinct. Group II is a method of detecting the levels of Tumor Necrosis Factor-alpha, Groups III-V are a method of treatment, and Group VI is a method of preparation of a medicament. A method of detecting, a method of treating and a method of preparation differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

6. Groups III-V are methods of treating different disorders with an antibody to Tumor Necrosis Factor-alpha. Group III is a neoplastic disease; Group IV is an inflammatory disorder; and Group V is inhibiting apoptosis. These Groups are distinct

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because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

7. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

Species Election

8. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

9. If Group I is elected, applicant is further required to elect ONE particular Tumor Necrosis Factor-alpha antibody AND to provide the following information with respect to the elected species of Tumor Necrosis Factor-alpha antibody:

- i) applicable heavy chain SEQ ID NO.;
- ii) applicable light chain SEQ ID NO.;
- iii) applicable heavy chain CDR1, CDR2, and CDR3 SEQ ID NO's; AND
- iv) applicable light chain CDR1, CDR2, and CDR3 SEQ ID NO's.

These species of Tumor Necrosis Factor-alpha antibodies are distinct because each antibody possesses a unique structure as determined both by its heavy and light chain sequences, and by the pairing of those sequences to produce the antigen binding site.

10. If one of Group II or V is elected, drawn to a method of using a Tumor Necrosis Factor-alpha antibody, applicant is further required to elect ONE particular Tumor Necrosis Factor-alpha antibody AND to provide the following information with respect to the elected species of Tumor Necrosis Factor-alpha antibody:

- i) applicable heavy chain SEQ ID NO.;
- ii) applicable light chain SEQ ID NO.;
- iii) applicable heavy chain CDR1, CDR2, and CDR3 SEQ ID NO's; AND
- iv) applicable light chain CDR1, CDR2, and CDR3 SEQ ID NO's.

These species of Tumor Necrosis Factor-alpha antibodies are distinct because each antibody possesses a unique structure as determined both by its heavy and light chain sequences, and by the pairing of those sequences to produce the antigen binding site.

11. If Group III is elected, drawn to a method of using a Tumor Necrosis Factor-alpha antibody, applicant is required to elect a specific neoplastic disease, from the specific neoplastic diseases recited in Claim 48 **AND** applicant is further required to elect **ONE** specific Tumor Necrosis Factor-alpha antibody, from the specific Tumor Necrosis Factor-alpha antibodies **AND** to provide the following information with respect to the elected species of Tumor Necrosis Factor-alpha antibody:

- i) applicable heavy chain SEQ ID NO.;
- ii) applicable light chain SEQ ID NO.;
- iii) applicable heavy chain CDR1, CDR2, and CDR3 SEQ ID NO's.; **AND**
- iv) applicable light chain CDR1, CDR2, and CDR3 SEQ ID NO's.

12. If Group IV is elected, drawn to a method of using a Tumor Necrosis Factor-alpha antibody, applicant is required to elect a specific immuno-mediated inflammatory disease, from the specific immuno-mediated inflammatory disease recited in Claim 50 **AND** applicant is further required to elect **ONE** specific Tumor Necrosis Factor-alpha antibody, from the specific Tumor Necrosis Factor-alpha antibodies **AND** to provide the following information with respect to the elected species of Tumor Necrosis Factor-alpha antibody:

- i) applicable heavy chain SEQ ID NO.;
- ii) applicable light chain SEQ ID NO.;
- iii) applicable heavy chain CDR1, CDR2, and CDR3 SEQ ID NO's.; **AND**
- iv) applicable light chain CDR1, CDR2, and CDR3 SEQ ID NO's.

13. If Group VI is elected, drawn to a method of preparation of a medicament, applicant is required to elect a specific neoplastic disease from the specific neoplastic diseases recited in Claim 53 OR a specific immuno-mediated inflammatory disease, from the specific immuno-mediated inflammatory diseases recited in Claim 55 AND applicant is further required to elect ONE specific Tumor Necrosis Factor-alpha antibody, from the specific Tumor Necrosis Factor-alpha antibodies AND to provide the following information with respect to the elected species of Tumor Necrosis Factor-alpha antibody:

- i) applicable heavy chain SEQ ID NO.;
- ii) applicable light chain SEQ ID NO.;
- iii) applicable heavy chain CDR1, CDR2, and CDR3 SEQ ID NO's; AND
- iv) applicable light chain CDR1, CDR2, and CDR3 SEQ ID NO's.

14. These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter. Further, the species of Tumor Necrosis Factor-alpha antibodies are distinct because each antibody possesses a unique structure as determined both by its heavy and light chain sequences, and by the pairing of those sequences to produce the antigen binding site.

15. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

16. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

17. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

18. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

19. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

20. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

21. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the

rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

22. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jo Ann Rinaudo whose telephone number is 571.272.8143. The examiner can normally be reached on M-F, 8:30AM - 5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571.272.0841. The fax phone number for the organization where this application or proceeding is assigned is 571.273.8300.

24. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

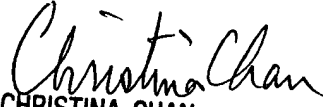
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Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jo Ann Rinaudo, Ph.D.

Patent Examiner

9/14/05


CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600